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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/553,948

12/04/2006

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P28700

6527

7055 7590 12/30/2009  
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EXAMINER

ARCHIE, NINA

ART UNIT

PAPER NUMBER

1645

NOTIFICATION DATE

DELIVERY MODE

12/30/2009

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

gbpatent@gbpatent.com  
pto@gbpatent.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/553,948	<b>Applicant(s)</b> SATO ET AL.	
	<b>Examiner</b> Nina A. Archie	<b>Art Unit</b> 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 10 June 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-5 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☒ Claim(s) 3-4 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)                        | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

***DETAILED ACTION***

1. This Office is responsive to Applicant's amendment and response filed 9-9-09. Claims 1-5 are pending and under examination.

***Rejections Withdrawn***

2. In view of the Applicant's amendment and remark the following rejections are withdrawn.

a) Rejection to claims 1-2 under 35 U.S.C. 102(b) as being anticipated by Zharkov et al 2000 Vol. 275 NO. 37 pgs. 28607-28617 is withdrawn in light of applicants' arguments.

b) Rejection of claims 1 and 5 under 35 U.S.C. 103(a) as being unpatentable over Zharkov et al 2000 Vol. 275 NO. 37 pgs. 28607-28617 and Krieg et al WO/1998/018810 Date May 7, 1998 is withdrawn in light of applicants' arguments.

***New Grounds of Objections and Rejections***

***Claim Objections***

3. Claims 3-4 are objected to for being dependent on a rejected base claim. Claims 3-4 in regards to the specific SEQ ID NOs: 1-4 are free of the art of record.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-2 are rejected under 35 U.S.C. 102(b) as being anticipated by Gaffney et al 1984 Biochemistry Vol. 23 pgs. 5686-5691.

Claims 1-2 are drawn to a polynucleotide comprising a CpG motif wherein guanine is methylated and the methylated guanine is 6-O-methyl-2'-deoxyguanosine (claim 1), wherein the length is 8-100 nucleotides (claim 2).

Gaffney et al teach a polynucleotide comprising a CpG motif wherein guanine is methylated and the methylated guanine is 6-O-methyl-2'-deoxyguanosine, wherein the length is 12 oligonucleotides (see pg. 5686 columns 1-2).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gaffney et al 1984 Biochemistry Vol. 23 pgs. 5686-5691 and Krieg et al WO/1998/018810 Date May 7, 1998.

Claims 1 and 5 are drawn to a polynucleotide comprising a CpG motif wherein guanine is methylated and the methylated guanine is 6-O-methyl-2'-deoxyguanosine (claim 1), wherein a pharmaceutical composition which comprises the polynucleotide as an active ingredient and at least one pharmaceutically acceptable excipient (claim 5).

Gaffney et al teach a polynucleotide comprising a CpG motif wherein guanine is methylated and the methylated guanine is 6-O-methyl-2'-deoxyguanosine, wherein the length is 12 oligonucleotides (see pg. 5686 columns 1-2).

Gaffney et al does not teach a polynucleotide, wherein a pharmaceutical composition which comprises the polynucleotide as an active ingredient and at least one pharmaceutically acceptable excipient.

Krieg et al teach methylated oligonucleotides (polynucleotide) comprising a CpG motif, wherein the length is 8 to 100 nucleotides. Krieg et al further teach a pharmaceutical composition

Art Unit: 1645

which comprises the polynucleotide as an active ingredient and at least one pharmaceutically acceptable excipient (see Krieg et al in its entirety and claims).

It would have been prima facie obvious at the time the invention was made to produce a polynucleotide as taught Gaffney et al and to incorporate into a pharmaceutical composition as taught by Krieg et al in order to induce an immune response.

One would have reasonable expectation of success because a polynucleotide CpG motif is well known in the art as disclosed by Krieg et al.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. As to independent claim 2, reciting the phrase “the length”, this phrase is confusing. Applicant has attempted to claim the length of the polynucleotide, however, it is unclear how to interpret the length when claim recites the limitation “8 to 100 nucleotides” which comprises more than one length. Therefore, the skilled artisan would not be readily apprised of the metes and bounds of the claim language regarding the length as set forth supra or how to assess such. Clarification in this regard is required.

### ***Conclusion***

7. No claims allowed.

Claims 3-4 are free of the art.

8. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Art Unit: 1645

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nina A. Archie whose telephone number is 571-272-9938. The examiner can normally be reached on Monday-Friday 8:30-5:00p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner supervisor, Robert Mondesi can be reached on 571-272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Nina A Archie

Examiner

GAU 1645

REM 3B31

/Robert A. Zeman/

for Nina Archie, Examiner of Art Unit 1645